PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0	Pack of 20 tablets

S1	Pack of 100 tablets

OBIDENT 500 TABLETS, tablet

Paracetamol

Sugar free

Read all of this leaflet carefully because it contains important information for you

OBIDENT 500 TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use OBIDENT 500 TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OBIDENT 500 TABLETS with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What OBIDENT 500 TABLETS is and what it is used for

2. What you need to know before you take OBIDENT 500 TABLETS

3. How to take OBIDENT 500 TABLETS

4. Possible side effects

5. How to store OBIDENT 500 TABLETS

6. Contents of the pack and other information

1. What OBIDENT 500 TABLETS is and what it is used for

OBIDENT 500 TABLETS contains a medicine called paracetamol, which belongs to a group of medicines called analgesics and antipyretics. OBIDENT 500 TABLETS is used to treat the following conditions:

- To relieve mild to moderate pain and fever, such as headaches, toothache and pain associated with colds and flu.

2. What you need to know before you are given OBIDENT 500 TABLETS

Do not take OBIDENT 500 TABLETS if:

- you are hypersensitive (allergic) to paracetamol or any of the other ingredients of OBIDENT 500 TABLETS (listed in **See what OBIDENT 500 TABLETS contains** below).
- You have been diagnosed severe liver function problems.

Warnings and precautions

Special caution should be taken with OBIDENT 500 TABLETS:

- If pain or fever persists or gets worse at the recommended dosage of OBIDENT 500 TABLETS, or if new symptoms occur.
- If you suffer from hepatitis (inflammatory condition of the liver).
- If you suffer from alcoholism.
- If you are recovering from any liver disease.
- If you have moderate kidney failure, or are on dialysis (treatment that performs functions of the kidneys).
- If you suffer with malnutrition (lack of sufficient nutrients in the body) or dehydration (significant loss of body fluids).

- If you have low levels of the antioxidant glutathione in the body.
- Do not use or give OBIDENT 500 TABLETS continuously without consulting a doctor or pharmacist or nurse:

  If you have pain for more than 7 days (5 days for children); and if you have fever for more than 3 days.

Other medicines and OBIDENT 500 TABLETS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Rifampicin and isoniazid (medicines for TB)
- Carbamazepine (for epilepsy or fits)
- Metoclopramide (for nausea and vomiting)
- Probenecid (for gout)
- Cholestyramine (for lowering cholesterol levels)
- Aspirin (for fever and pain)
- Warfarin (to thin the blood)

OBIDENT 500 TABLETS with food and drink and alcohol

Taking OBIDENT 500 TABLETS with alcohol should be avoided.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

OBIDENT 500 TABLETS is generally considered safe for use if you are pregnant and if you take OBIDENT 500 TABLETS daily or on most days.
OBIDENT 500 TABLETS is distributed into breastmilk in small amounts that are not considered to be harmful if you are breastfeeding your child.

Driving and using machines

It is generally safe to drive and use machinery while taking OBIDENT 500 TABLETS.

OBIDENT 500 TABLETS contains:

OBIDENT 500 TABLETS is sugar free.

3. How to take OBIDENT 500 TABLETS

Do not share medicines prescribed for you with any other person.
Always take OBIDENT 500 TABLETS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose is:

Children under 6 years: Not recommended.

Children 6 – 12 years: Give half to one tablet (250 mg to 500 mg) every 6 hours, if it is necessary. Not more than 4 doses to be given in any 24-hour period.

Children over 12 years: Give one tablet (500 mg) every 4 – 6 hours, if it is necessary.

Not more than 4 tablets (2000 mg) to be given in any 24-hour period.

Adults: Take one to two tablets (500 mg to 1000 mg) every 4 – 6 hours, if it is necessary.

Not more than 8 tablets (4000 mg) to be taken in any 24-hour period.

Swallow tablets with a glass of water.

Do not chew the tablets.

If you take more OBIDENT 500 TABLETS than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

Symptoms of overdosage include paleness of the skin, nausea, vomiting, lethargy, sweating and pain in the abdominal area. Mild symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Liver damage may become apparent 12 to 48 hours, or later, after ingestion.

Prompt treatment following overdosage is essential, even if you feel well.

If you forget to take OBIDENT 500 TABLETS

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

OBIDENT 500 TABLETS can have side effects.

Not all side effects reported for OBIDENT 500 TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OBIDENT 500 TABLETS, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking OBIDENT 500 TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to OBIDENT 500 TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Agranulocytosis (very low white blood cells called neutrophils in the blood). Symptoms of agranulocytosis may include:
    - Sores in the mouth, throat, or gastrointestinal tract.
    - Chronic infections of the gums, throat, or skin.
    - Fever.
    - Chills.
    - A drop in blood pressure, which may cause weakness or lightheadedness.
- Narrowing of the airways with breathing difficulties and wheezing (bronchospasm). These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes (symptoms of abnormal liver function).
- Inflammation of the pancreas with stomach pain, nausea and vomiting.

- Severe and sharp pain in lower back and/or side.
- Sudden decrease in amount of urine.
- Cloudy urine.
- Skin rash accompanied by fever and sores in the mouth.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects

- A decrease in the number of white blood cells.
- Reduction in number of red blood cells, white blood cells and platelets (pancytopenia).
- A decrease in the number of platelets leading to blood clotting problems.
- Unusual tiredness or weakness.
- Skin rash with abnormal redness of the skin or hives (itchy rash).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OBIDENT 500 TABLETS.

5. How to store OBIDENT 500 TABLETS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Protect from light and moisture.

Store in the original package/container.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use OBIDENT 500 TABLETS after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OBIDENT 500 TABLETS contains

The active substance in each tablet is paracetamol 500 mg.

The other ingredients are:

Colloidal anhydrous silica, dioctyl sodium sulphosuccinate, magnesium stearate, maize starch, polyvinylpyrrolidone quinoline yellow (E104), brilliant blue (E133) and indigo carmine (E132).

What OBIDENT 500 TABLETS looks like and contents of the pack

Light green, slightly mottled, round, flat, beveled edge tablets, plain on one side and break line on the other side.

OBIDENT 500 TABLETS is packed in a blister comprising of plain aluminium foil with VMCH coating and clear transparent PVC film and placed in a preprinted carton along with a patient information leaflet.

Pack sizes: 20 and 100 tablets.

Holder of Certificate of Registration

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